CLAIMS

We claim:

1. A combination of antichlamydial agents comprising at least two agents, each of which is effective against a different phase of chlamydial life cycle.

2. The combination according to Claim 1 wherein the agents are selected from the group consisting of:
   a) agents effective against cryptic phase of chlamydial life cycle;
   b) agents effective against elementary body phase of chlamydial life cycle; and
   c) agents effective against replicating phase of chlamydial life cycle.

3. The combination according to Claim 1 wherein the agents are assembled as an admixture.

4. The combination according to Claim 1 wherein the agents are copackaged individually.

5. The combination according to Claim 1 wherein the agents are instructionally assembled.

6. The composition according to Claim 1 further comprising antiinflammatory agent, immunosuppressive agent, Vitamin C or combinations thereof.

7. A combination of antichlamydial agents for use in managing chlamydial infection or prophylaxis thereof; wherein the combination comprises at least two agents, each of which is effective against a different phase of chlamydial life cycle.

8. method of treating a chlamydial infection or disease associated therewith comprising treating the patient to reduce the acellular load of infectious EBs.

9. A method of treating a chlamydial infection or disease associated therewith comprising treating the patient with one or more antibiotics for not less than 45 days.

10. A pharmaceutical composition comprising at least two agents, each of which is effective against a different phase of chlamydial life cycle.

11. The pharmaceutical composition according to Claim 10 wherein the agents are selected from the group consisting of:

a) agents effective against cryptic phase of chlamydial life cycle;

b) agents effective against elementary body phase of chlamydial life cycle; and

c) agents effective against replicating phase of chlamydial life cycle.

12. The pharmaceutical composition according to Claim 10 wherein the agents are formulated together in a physiologically acceptable vehicle.

13. A pharmaceutical composition for use in managing chlamydial infection or prophylaxis thereof; wherein the composition comprises at least two agents, each of which is effective against a different phase of chlamydial life cycle.

14. The pharmaceutical composition according to Claim 13 further comprising antiinflammatory agent, immunosuppressive agent, Vitamin C or combinations thereof.

15. A method for eliciting a protective immune response to *Chlamydia* infection in an animal or human by administering to an infected animal or human at least two agents, each of which is effective against a different phase of chlamydial life cycle until the human or animal no longer tests positive for Chlamydia.

16. A diagnostic kit or pack comprising materials adequate to perform one or more of the following:

a) antibody assays against recombinant MOMP;

b) antibody assays against specific antigenic peptides described in Figures 3, 4 and 5;

c) antigen capture assays directed against MOMP or the peptides described in Figures 3, 4 and 5;

d) DNA amplification assays for chlamydial genes; and

e) Western blot used as a confirmatory.

17. The kit or pack of Claim 16, wherein the antibody assays are ELISAs.

18. A pharmaceutical pack of therapeutic agents for management of *Chlamydia* infection, comprising at least two agents, each of which is effective against a different phase of chlamydial life cycle.

19. The pharmaceutical pack according to Claim 18 wherein the agents are selected from the group consisting of:

a) agents effective against cryptic phase of the chlamydial life cycle;

b) agents effective against elementary body phase of the chlamydial life cycle; and

c) agents effective against replicating phase of the chlamydial life cycle.

20. The pharmaceutical pack according to Claim 18 further comprising antiinflammatory agent, immunosuppressive agent, Vitamin C, or combinations thereof.

21. The pharmaceutical pack according to Claim 18 wherein the pack is a single unit dose.

22. The pharmaceutical pack according to Claim 18 wherein the agents are contained within the pack separately and/or as an admixture.

23. The pharmaceutical pack according to Claim 18 wherein the pack is a single blister pack or a single vial.

24. The pharmaceutical pack according to Claim 18 wherein the pack comprises a plurality of unit dosages.

25. The pharmaceutical pack according to Claim 18 wherein the pack is a plurality of single blister packs or a plurality of single vials.

26. A method for treating biological material infected with *Chlamydia*, comprising contacting the biological material with at least two agents, each of which is effective against a different phase of chlamydial life cycle.

27. The method according to Claim 26 wherein the agents are selected from the group consisting of:
    a) agents effective against cryptic phase of chlamydial life cycle;
    b) agents effective against elementary body phase of chlamydial life cycle; and
    c) agents effective against replicating phase of chlamydial life cycle.

28. The method according to Claim 26 wherein the agent effective against the elementary body phase is a disulfide reducing agent.

29. The method according to Claim 29, wherein the agent effective against the cryptic phase is a nitroaromatic compound.

30. The method according to Claim 26, wherein the nitroaromatic compound is selected from the group consisting of nitroimidazoles, nitrofurans, analogs, derivative and combinations thereof.

31. A method for managing chlamydial infection in an individual in need thereof, comprising administering at least two agents, each of which is effective against a different phase of chlamydial life cycle.

32. The method according to Claim 31 wherein the agents are selected from the group consisting of:
    a) agents effective against cryptic phase of chlamydial life cycle;
    b) agents effective against elementary body phase of chlamydial life cycle; and

c) agents effective against replicating phase of chlamydial life cycle.

33. A method for diagnosing disease associated with *Chlamydia* infection comprising diagnosing the *Chlamydia* infection in an individual, wherein the disease is an autoimmune disease, an inflammatory diseases or a disease that occurs in immunocompromised inviduals.

34. A method for treating disease associated with *Chlamydia* infection comprising treating the *Chlamydia* infection in an individual in need thereof, comprising administering a combination of antichlamydial agents that are effective against at least two phases of the chlamydial life cycle. wherein the disease is an autoimmune disease, an inflammatory diseases and disease that occurs in immunocompromised individuals.

35. The method according to Claim 34 wherein the agents are selected from at least two different agents from at least two of the following groups:

a) agents effective against cryptic phase of chlamydial life cycle;

b) agents effective against elementary body phase of chlamydial life cycle; and

c) agents effective against replicating phase of chlamydial life cycle.

36. The method according to Claim 35 wherein the infection is a *Chlamydia pneumoniae* infection.

37. An assay for identifying an agent which is capable of inhibiting chlamydial infection, comprising the steps of:

a) preparing tissue culture cells infected with *Chlamydia* in the absence of cycloheximide;

b) allowing the *Chlamydia* to replicate;

c) adding a test agent;

d) isolating chlamydial nucleic acid from the cells;

e) amplifying the chlamydial nucleic acid by a nucleic acid amplification technique; and

f) evaluating the presence or absence of amplified chlamydial nucleic acid;

wherein the absence of amplified chlamydial nucleic acids is indicative that the agent is capable of inhibiting chlamydial infection.

38. The assay of Claim 37 wherein the amplification technique is PCR.

39. A method of identifying cells containing cryptic form of *Chlamydia* comprising the steps of:

a) treating cultured cells, thought to be infected with chlamydia, with a disulfide reducing agent;

b) subjecting cultured cells to protease digestion;

c) exposing cells to appropriate polymerase, dNTPs and primers for DNA amplification of a chlamydial protein;

d) exposing the cells to a reporter molecule enzyme;

e) exposing the cells to an appropriate substrate for the reporter enzyme; and

f) determining the presence of cryptic form of *Chlamydia* by visualizing the amplified DNA encoding a chlamydial protein.

40. A method according to Claim 39, wherein the *Chlamydia* is *Chlamydia pneumoniae*.

41. A method according to Claim 40, wherein the primers of step c) are CHLMOMPDB2 and CHLMOMPCB2.

42. A method of identifying cells containing cryptic form of *Chlamydia* comprising the steps of:

a) treating cultured cells, thought to be infected with chlamydia, with guanidine thiocyanate;

b) exposing cells to appropriate polymerase, dNTPs and primers for DNA amplification of a chlamydial protein;

c) exposing the cells to a reporter molecule enzyme;

d) exposing the cells to an appropriate substrate for the reporter enzyme; and

e) determining the presence of cryptic form of *Chlamydia* by visualizing the amplified DNA encoding a chlamydial protein.

43. An assay for identifying an agent which is effective against cryptic form of *Chlamydia* comprising the steps of:

a) treating cultured cells grown in the absence of cycloheximide, thought to be infected with chlamydia, with a disulfide reducing agent;

b) allowing the chlamydia to replicate;

c) adding a test agent;

d) subjecting cultured cells to protease digestion;

e) exposing cells to appropriate polymerase, dNTPs and primers for DNA amplification of a chlamydial protein;

f) exposing the cells to a reporter molecule enzyme;

g) exposing the cells to an appropriate substrate for the reporter enzyme;

h) determining the presence of cryptic form of *Chlamydia* by visualizing the amplified DNA encoding a chlamydial protein;

wherein the absence of amplified chlamydial nucleic acids is indicative that the agent is capable of inhibiting chlamydial infection.

44. An assay according to Claim 43, wherein the appropriate primers of step a) are CHLMOMPDB2 and CHLMOMPCB2.

45. A method for activating macrophages or monocytes in which their infection fighting ability has been compromised by a *Chlamydia* infection, comprising treating the Chlamydia infection by contacting the infected macrophages or monocytes with an antichlamydial agent.

46. A method of treating biological material infected with *Chlamydia*, comprising contacting the biological material with at least one agent selected from the following groups:

a) agents effective against the cryptic phase;

b) agents effective against elementary body phase;

c) ethambutol and anules and derivatives thereof and isonicatinic acid cogeners;

d) agents first identified as inhibiting chlamydial infection by the method of Claim 36.

47. A method of detecting chlamydial elementary bodies in a sample comprising contacting the sample with a disulfide reducing agent before using a DNA

amplification technique to detect chlamydial DNA in the sample.

48. A method of detecting chlamydial elementary bodies in a sample comprising performing on the sample an antigen capture assay directed against MOMP or the peptides described in Figures 3, 4 and 5.

49. The method of Claim 48, wherein the sample is contacted with a disulfide reducing agent before the assay is performed.

50. A peptide of Figure 3, 4 and 5.

51. Antichlamydia agent identified by the assay of Claim 37.

52. Antichlamydia agent identified by the assay of Claim 43.

53. The method of Claim 46 wherein the agent effective against the cryptic phase is a nitroaromatic compound.

54. The method of Claim 46 wherein the agent effective against the elementary body phase is a disulfide reducing agent.

55. A method of determining the status of a patient or monitoring and/or modifying the course of therapy for chlamydia infection comprising the results of one or more assays made contemporaneously or sequentially, wherein the assays are selected from the group consisting of:

a) antibody assays against recombinant MOMP;
b) antibody assays against specific antigenic peptides described in Figures 3, 4 and 5;
c) antigen capture assays directed against MOMP or the peptides described in Figures 3, 4 and 5;
d) DNA amplification assays for chlamydial genes; and
e) Western blot used as a confirmatory.

56. The method of Claim 55, wherein the antibody assays are ELISAs.

57. The method of Claim 55 wherein DNA amplification assay is PCR.

58. The method of Claim 55 wherein DNA amplification assay amplifies the MOMP gene.

59. The method of Claim 55 wherein more than one assay is used.

60. The method of Claim 55 wherein specific antibody measures are obtained against IgA, IgE, IgM and/or IgG.

61. An assay for identifying an agent which is capable of inhibiting chlamydial infection in a patient or an animal, comprising the steps of:
a) obtaining a biological material sample from a patient from which the infectious organism is extracted and applied to target cells for culturing;
b) allowing the *Chlamydia* to replicate;
c) adding one or more agents;

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d) isolating chlamydial nucleic acid from the cells with the use of protease and reducing agents, or guanidine thiocynate;

e) amplifying the chlamydial nucleic acid by a nucleic acid amplification technique; and

f) evaluating the presence or absence of amplified chlamydial nucleic acid;

wherein the absence of amplified chlamydial nucleic acids is indicative that the agent or agents is capable of inhibiting chlamydial infection.

62. A method according to Claim 61 wherein the *Chlamydia* is *Chlamydia pneumonia*.

63. A method according to Claim 61 wherein the primers of step d) are CHLMOMPDB2 and CHLMOMPCB2.

64. A method according to Claim 61 wherein at least two or more probes are used to reduce false positives.

65. A method of treating a chlamydial infection or disease asociated therewith comprising treating the patient to reduce the acellular load of infectious EBs.

66. A method of treating a chlamydial infection or disease associated therewith comprising treating the patient with one or more antibiotics for not less than 45 days.

67. A method for determining the effectiveness of an antichlamydial agent, comprising the steps of:

a) obtaining serum or whole blood from an animal or human that has undergone therapy for eliminating

Chlamydia infection; wherein the therapy comprises administering to the animal or human at least two agents effective against a different phase of the chlamydial life cycle;

b) introducing the serum or whole blood into an Chlamydia-free organism; and

c) determining bacterial response to chlamydial challenge in the *Chlamydia*-free organism.